

DEBTORS/NEWCO OPERATING INJUNCTION

I. DEFINITIONS

- A. “Bankruptcy Court” or “Court” shall mean the court presiding over the chapter 11 proceedings *In re Purdue Pharma L.P. et al.*, Case No. 19-23649-RDD (Bankr. S.D.N.Y.).
- B. “CDC Guideline Recommendations” shall mean the 12 enumerated Recommendations published by the U.S. Centers for Disease Control and Prevention (CDC) for the prescribing of opioid pain medication for patients 18 and older in primary care settings as part of its 2016 Guideline for Prescribing Opioids for Chronic Pain (CDC Guidelines), as updated or amended by the CDC.
- C. “Chapter 11 Plan of Reorganization” or “Plan of Reorganization” or “Plan” shall mean the ~~final version entered~~ Eleventh Amended Plan filed on August 31, 2021 as may be further amended in *In re Purdue Pharma L.P.*.
- D. “Company” shall mean the Debtors as defined in these chapter 11 proceedings *In re Purdue Pharma L.P. et al.*, Case No. 19-23649-RDD (S.D.N.Y.). Following the Effective Date, “Company” shall mean “NewCo,” a newly formed Delaware limited liability company to be created in accordance with Section 5.4 of the Plan to directly or indirectly receive the NewCo Transferred Assets and operate such NewCo Transferred Assets in accordance with the NewCo Operating Agreement, the NewCo Governance Covenants and the NewCo Operating Injunction.
- E. “Confirmation Order” shall mean the order of the Bankruptcy Court (or other court of competent jurisdiction) confirming the Chapter 11 Plan.
- F. “Downstream Customer Data” shall mean transaction information that the Company collects relating to the Company’s direct customers’ sales to downstream customers, including but not limited to chargeback data tied to the Company providing certain discounts, “867 data,” and IQVIA data.
- G. “Effective Date” means the date on which the Plan of Reorganization becomes effective.
- H. “Governance Covenants” shall have the meaning set forth in NewCo’s Operating Agreement.
- I. “Health Care Provider” shall mean any U.S.-based physician or other health care practitioner who is licensed to provide health care services or to prescribe pharmaceutical products and any medical facility, medical practice, hospital, clinic or pharmacy.
- J. “Including but not limited to,” when followed by a list or examples, shall mean that list or examples are illustrative instances only and shall not be read to be restrictive.

- K. “In-Kind Support” shall mean payment or assistance in the form of goods, commodities, services, or anything else of value.
- L. “Lobby” ~~and “Lobbying”~~ shall ~~have the same meaning as~~ mean to engage in “lobbying activities” ~~and/or~~ “lobbying contacts” under the federal lobbying disclosure act, 2 U.S.C. § 1602 *et seq.*, and any analogous state or local provisions governing the person or entity being lobbied in that particular state or locality. As used in this injunction, “Lobby” ~~and “Lobbying”~~ ~~include~~ includes Lobbying directly or indirectly, through grantees or Third Parties.
- M. “NewCo Disposition Event” shall have the meaning assigned to the term “Disposition Event” as set forth in the NewCo Operating Agreement.
- N. “NewCo Operating Agreement” shall have the meaning set forth in the Plan of Reorganization.
- O. “Opioid(s)” shall mean all natural, semi-synthetic, or synthetic chemicals that interact with opioid receptors and act like opium. For the avoidance of doubt, the term Opioid shall not include the opioid antagonists naloxone and nalmeferene.
- P. “Opioid Product(s)” shall mean all current and future medications containing Opioids approved by the U.S. Food & Drug Administration (FDA) and listed by the Drug Enforcement Administration (DEA) as Schedule II, III, or IV drugs pursuant to the federal Controlled Substances Act, including but not limited to codeine, fentanyl, hydrocodone, hydromorphone, meperidine, morphine, oxycodone, oxymorphone, tapentadol, and tramadol.
- Q. “OUD” shall mean opioid use disorder defined in the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5)*, as updated or amended.
- R. “PHI Product(s)” shall have the meaning set forth in the NewCo Operating Agreement, which for the avoidance of doubt includes, buprenorphine-naloxone combination tablets, over-the-counter naloxone nasal spray, injectable nalmeferene, and any other medicines as determined by NewCo’s Board provided that such medicines must be approved by the FDA for treatment of opioid addiction, ~~opioid dependence~~ and/or reversing opioid overdoses, but for purposes of this injunction does not include methadone and generic versions of Subutex® sublingual buprenorphine tablets.
- S. “Promote,” “Promoting,” and “Promotion” shall mean dissemination of information or other practices intended or that could be reasonably anticipated to influence prescribing practices in a manner that increases sales, prescriptions, or the utilization of prescription products.
- T. “Qualified Researcher” shall mean any researcher holding a faculty appointment or research position at an institution of higher education, a research organization, a nonprofit organization, or a government agency.

- U. “Section” shall mean, unless the context requires otherwise, a Section of this injunction.
- V. “Shareholder Released Parties” shall mean the Estate of Beverly Sackler, David A. Sackler, Ilene Sackler, the Estate of Jonathan D. Sackler, Kathe Sackler, Mortimer D.A. Sackler, Richard S. Sackler, Theresa Sackler, any trusts of which any of the foregoing are beneficiaries, and the trustees thereof (solely in their capacities as such), each Shareholder Party and each other entity or person that directly or indirectly owns equity in, or has voting control over, any of the Debtors, and in the event of the death of a Shareholder Released Party who is a natural person, other than a natural person who is a Shareholder Released Party solely in the capacity as a trustee, the estate of such person.
- W. “State Monitor Committee” shall mean a bipartisan, volunteer committee comprising representatives from 5-7 States.
- X. “Suspicious Order” shall have the same meaning as provided by the Controlled Substances Act, 21 U.S.C. §§ 801-904, and the regulations promulgated thereunder, final DEA administrative decisions that are published in the Federal Register, and analogous state laws and regulations.
- Y. “Third Party” shall mean any person or entity other than the Company or a government entity.
- Z. “Treatment of Pain” shall mean the provision of therapeutic modalities to alleviate or reduce pain.

II. SCOPE AND ENFORCEMENT

- A. This injunction shall apply to and be binding on NewCo on the Effective Date; and on any transferee or successor to, or subsequent operator of, all or any portion of NewCo’s Opioid business (a “Transferee/Successor”) as set forth below.
- B. The Debtors and NewCo consent to the entry of a final judgment or consent order, substantially in the form of this injunction, imposing all of the provisions of this injunction in each state and territorial court on the Debtors, NewCo and any Transferee/Successor, at any time after the Effective Date (the “Consent Judgment”), as well as to the jurisdiction of those state and territorial courts with respect to a Consent Judgment. A Consent Judgment shall apply to and be binding on NewCo after the Effective Date; and on any Transferee/Successor.
- C. Until this injunction is effective, the Voluntary Injunction initially entered on November 6, 2019 in *Purdue Pharma L.P. v. Massachusetts*, Adv. Pro. No. 19-08289 (Bankr. S.D.N.Y) as Exhibit 1 to the Second Amended Order Pursuant to 11 U.S.C. § 105(a) Granting Motion for a Preliminary Injunction and re-entered thereafter, shall remain in full force and effect on the Company and NewCo.
- D. Without limiting the foregoing:

1. NewCo shall be required to obtain the consent of any Transferee/Successor to be bound by this injunction and to submit to the jurisdiction of this Court and each state and territorial court for enforcement of the terms of this injunction as a condition to a transfer of all or any portion of NewCo's Opioid business.
2. Nothing in this injunction applies to the operation of a Transferee/Successor's pre-existing Opioid business. Any Transferee/Successor shall be subject only to Sections III.A-C and III.E-H.
3. Nothing requires that this injunction be enforced exclusively in this Court or limits the jurisdiction of any state or territorial court to enforce the terms of this injunction.

III. INJUNCTIVE RELIEF

A. Ban on Promotion

1. The Company shall not engage in the Promotion of Opioids or Opioid Products, including but not limited to, by:
 - a. Employing or contracting with sales representatives or other persons to Promote Opioids or Opioid Products to Health Care Providers or patients.
 - b. Using speakers, key opinion leaders, thought leaders, lecturers, and/or speaking events for Promotion of Opioids or Opioid Products.
 - c. Sponsoring, or otherwise providing financial support or In-Kind Support to medical education programs that include references to Opioids or Opioid Products.
 - d. Creating, sponsoring, operating, controlling, or otherwise providing financial support or In-Kind Support to any website, network, and/or social or other media account for the Promotion of Opioids or Opioid Products.
 - e. Creating, sponsoring, distributing, or otherwise providing financial support or In-Kind Support for materials Promoting Opioids or Opioid Products, including but not limited to brochures, newsletters, pamphlets, journals, books, and guides.
 - f. Creating, sponsoring, or otherwise providing financial support or In-Kind Support for advertisements that Promote Opioids or Opioid Products, including but not limited to internet advertisements or similar content, and providing hyperlinks or otherwise directing internet traffic to advertisements.
 - g. Engaging in Internet search engine optimization or other techniques designed to Promote Opioids or Opioid Products, including by improving

rankings or making content appear among the top results in an Internet search or otherwise be more visible or more accessible to the public on the Internet.

- h. Utilizing electronic health records software or other digital health platforms to create alerts, workflows, or disseminate information known or reasonably expected to increase utilization of Opioids or Opioid Products.
- 2. Notwithstanding Sections III.A.1 and III.C, the Company may:
 - a. Maintain corporate websites.
 - b. Maintain a website for any Opioid Product that contains principally the following content: the FDA-approved package insert, medication guide, and labeling, and a statement directing patients or caregivers to speak with a licensed Health Care Provider; Risk Evaluation and Mitigation Strategy (REMS) materials; and contact information to report an adverse event or product complaint.
 - c. Provide information or support the provision of information as expressly required by law, settlement, court order or any state or federal government agency, including providing all information necessary in order for the Company to comply with its regulatory obligations pursuant to the Federal Food, Drug, and Cosmetic Act or the Controlled Substances Act, and/or provide information about legal proceedings involving the Company.
 - d. Engage and compensate Health Care Providers or other Third Parties to assist the Company in responding to, preparing for and participating in any of the following activities held by any state or federal government or state or federal agencies or regulators, including the FDA: advisory committees, working groups, meetings and or/ hearings.
 - e. Provide the following by mail, electronic mail, on or through the Company's corporate or product websites or through other electronic or digital methods: FDA-approved package insert, medication guide, approved labeling for Opioid Products, REMS materials or other prescribing information for Opioid Products that are published by a state or federal government agency. State materials may be provided only within the applicable state.
 - f. Provide scientific and/or medical information in response to an unsolicited request by a Health Care Provider concerning Opioid Products consistent with the recommendations set forth in the FDA's Draft Guidance for Industry, *Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices* (Dec. 2011, as updated or amended by the FDA) and Guidance for Industry, *Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific*

Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices (Jan. 2009, as updated or amended by the FDA). Such responses should be handled by medical or scientific personnel at the Company who are independent from the sales or marketing departments.

- g. Provide a response to any unsolicited question or request from a patient or caregiver, directing the patient or caregiver to the FDA-approved labeling and to the extent that the question cannot be answered solely by reference to a specific provision of the FDA-approved labeling, providing a response that is truthful, balanced, non-misleading and fully consistent with the FDA-approved labeling or recommending the patient or caregiver speak with a licensed Health Care Provider without naming any specific provider or healthcare institution; or directing the patient or caregiver to speak with their insurance carrier regarding coverage of an Opioid Product.
- h. Provide information to a payor, formulary committee, distributor, or other similar entity with knowledge and expertise in the area of health care economics concerning the cost or availability of a Company Opioid Product, including the costs compared to the cost of an Opioid Product manufactured or distributed by another company. Such information may include information about the stocking of the Opioid Product as described in the FDA-approved labeling; tier status; applicable prescribing guidelines that are consistent with the FDA-approved labeling; step-edits for Opioid Products; restrictions; and/or prior authorization status concerning an Opioid Product. Provided further that information provided pursuant to this subparagraph shall also be posted on the website permitted by Section III.A.2.b, except for information that is commercially sensitive or otherwise confidential, which instead shall be provided to the Monitor and the State Monitor Committee.
- i. Sponsor or provide financial support or In-Kind Support for an accredited or approved continuing medical education program required by either an FDA-approved REMS program or other federal or state law or regulation in accordance with applicable requirements, settlement with a governmental entity, or court order, through an independent Third Party, which shall be responsible for the continuing medical education program's content without the participation of the Company.
- j. Provide rebates, discounts, fees and other customary pricing adjustments to DEA-registered customers and contracting intermediaries, such as Buying Groups, Group Purchasing Organizations, Managed Care Plans and Pharmacy Benefit Managers, except as prohibited by Section III.E.
- k. Promote PHI Products, and provide information about, discuss, or comment on, issues regarding mechanisms for preventing opioid abuse

and misuse, including the prevention, education and treatment of opioid overdose. Except that the Company shall not:

(i) Employ or contract with sales representatives to detail PHI Products (i.e., through direct interaction, whether in-person or virtual, with individual prescribing or dispensing health care professionals or their staffs) who are compensated based on sales or volume of PHI Products. The Company will document interactions related to PHI Products between Company sales representatives and health care professionals or their staffs and will retain documents and information relating to those communications; and/or

(ii) In addition to Section III.A.2.k.i, with regard to PHI Products that are Opioid Products indicated for the treatment of substance abuse disorders, employ or contract with sales representatives to detail such PHI Products (i.e., through direct interaction, whether in-person or virtual, with individual prescribing or dispensing health care professionals or their staffs). Nothing in this Section III.A.2.k.ii shall be construed to prohibit personal contact between non-sales representatives of the Company and health care professionals or their staffs regarding PHI Products that are Opioids. The Company will document interactions regarding PHI Products that are Opioids between Company non-sales representatives and health care professionals or their staffs and will retain documents and information relating to those communications.

(iii) Any and all documents and information relating to communications related to the activities described in Subsections (i) and (ii) of this Section III.A.2.k shall be ~~made available~~provided to the Monitor at his request for his review.

(iv) Nothing in this section shall be construed to permit the Promotion of methadone or generic versions of Subutex® sublingual buprenorphine tablets except pursuant to Sections III.A.2.a-j.

3. The Company shall not engage in the following specific Promotional activity relating to any products for the treatment of Opioid-induced side effects except as permitted by Section III.A.2.k, above:
- a. Employing or contracting with sales representatives or other persons to Promote products for the treatment of Opioid-induced side effects to Health Care Providers or patients.
 - b. Using speakers, key opinion leaders, thought leaders, lecturers, and/or speaking events for Promotion of products for the treatment of Opioid-induced side effects.
 - c. Sponsoring, or otherwise providing financial support or In-Kind Support to medical education programs relating to products for the treatment of

Opioid-induced side effects except as required by REMs, court orders or settlements.

- d. Creating, sponsoring, or otherwise providing financial support or In-Kind Support for advertisements that Promote products for the treatment of Opioid-induced side effects, including but not limited to internet advertisements or similar content, and providing hyperlinks or otherwise directing internet traffic to advertisements.
 - e. Engaging in any other Promotion of products for the treatment of Opioid-induced side effects in a manner that encourages the utilization of Opioids or Opioid Products or normalizes the use of Opioids or Opioid Products for chronic pain.
 - f. Utilizing electronic health records software or other digital health platforms to create alerts, workflows, or disseminate information known or reasonably expected to increase utilization of Opioids or Opioid Products.
4. Notwithstanding Section III.A.3, the Company may Promote Senokot® and Colace® or other non-prescription products to treat constipation so long as such Promotion does not explicitly or implicitly associate the product with Opioids or Opioid Products except for linking to the FDA label associated with that product.
5. Treatment of Pain
- a. The Company shall not, either through the Company or through Third Parties, engage in Promotion of the Treatment of Pain in a manner that directly or indirectly encourages the use of Opioids or Opioid Products.
 - b. The Company shall not, either through the Company or through Third Parties, Promote the concept that pain is undertreated in a manner that directly or indirectly encourages the use of Opioids or Opioid Products.
6. To the extent that the Company engages in conduct permitted by Section III.A.2, the Company shall do so in a manner that is:
- a. Consistent with the CDC Guideline Recommendations, as applicable.
 - b. Truthful, not misleading, accurate, and not deceptive.
7. For the avoidance of doubt, nothing in this injunction shall be construed or used to prohibit the Company from taking legal or factual positions in litigation, bankruptcy proceedings, investigations, regulatory actions, or other legal or administrative proceedings or prohibit or limit the Company's right to make public statements or respond to media reports or inquiries relating to any

litigation, bankruptcy proceedings, investigations, regulatory actions, or other legal, administrative, or legislative proceedings.

B. No Reward or Discipline Based on Volume of Opioid Sales

1. The Company shall not provide financial or non-financial incentives to its employees or discipline its employees based upon sales volume or sales quotas for Opioid Products.
2. The Company shall not offer or pay any remuneration (including any kickback, bribe, or rebate) directly or through a Third Party, to or from any person in return for the prescribing, sale, use or distribution of an Opioid Product. For the avoidance of doubt, this subparagraph shall not prohibit the provision of rebates and/or chargebacks to the extent permitted by Section III.A.2.j.
3. The Company's compensation policies and procedures shall be designed to ensure compliance with this injunction and other legal requirements.

C. Ban on Funding/Grants to Third Parties

Except with respect to PHI Products:

1. The Company shall not directly or indirectly provide financial support or In-Kind Support to any Third Party for the purpose of Promoting Opioids, Opioid Products, the Treatment of Pain, or products intended to treat Opioid-related side effects, including educational programs or websites that Promote Opioids, Opioids Products, the Treatment of Pain or products intended to treat Opioid-related side effects, but excluding financial support otherwise allowed by this injunction, including REMS, settlements, and court orders or as required by a federal or state agency.
2. The Company shall not operate, control, create, sponsor, provide financial support or In-Kind Support to any medical society or patient advocacy group relating to any Opioids, Opioid Products, the Treatment of Pain, or products intended to treat Opioid-related side effects, except with regard to REMS or to comply with settlements, court orders, or federal or state law.
3. The Company shall not provide links to any Third Party website or materials or otherwise distribute materials created by a Third Party relating to any Opioids, Opioid Products, the Treatment of Pain, or products intended to treat Opioid-related side effects.
4. The Company shall not use or pay any Third Party to engage in any activity that the Company itself would be prohibited from engaging in pursuant to the injunction.
5. The Company shall not enter into any contract or agreement with any person or entity or otherwise attempt to influence any person or entity in such a manner that

has the purpose or likely effect of limiting the dissemination of information regarding the risks and side effects of using Opioids.

6. The Company shall not compensate or provide In-Kind Support to Health Care Providers or organizations to advocate for formulary access or treatment guideline changes that would have the effect of increasing access to any Opioid Product by third-party payors, *i.e.*, any entity, other than an individual, that pays or reimburses for the dispensing of prescription medicines, including but not limited to managed care organizations and pharmacy benefit managers. For the avoidance of doubt, nothing herein shall prohibit the Company from compensating Third Parties for engaging in conduct otherwise permitted under this injunction.
7. No current director, officer, or management-level employee of the Company may serve as a director, board member, employee, agent, or officer of any entity that engages in Promotion relating to Opioids, Opioid Products, the Treatment of Pain, or products intended to treat Opioid-related side effects except insofar as such service would be consistent with Section III.A.2. or III.A.4, or except for services relating to (i) the treatment of OUD, (ii) the prevention, education or treatment of opioid abuse, addiction or overdose, including medication-assisted treatment for opioid addiction and/or (iii) rescue medication for opioid overdose.
8. The Company shall play no role in appointing persons to the board, or hiring persons to the staff, of any entity that principally engages in Promotion relating to any Opioids, Opioid Products, the Treatment of Pain, or products intended to treat Opioid-related side effects except as otherwise permissible under Section III.A.4.
9. The Company shall ensure that any employee serving on the board of any organization that engages in lobbying or educating state and federal officials on policies and regulations, the impact of which would be to more easily enable or Promote the use of Opioids or Opioid Products, recuse himself/herself from any board discussion or decisions relating to Opioids, including any determinations the organization may make related to lobbying efforts with respect to opioids. Further, the Company shall ensure that any such employees will refrain from participation in any working group of such organization that focus on the Promotion of Opioids or Opioid Products or which focus on issues that would otherwise not be permitted under this injunction.
10. For the avoidance of doubt, nothing in Section III.C shall be construed or used to prohibit the Company from providing financial or In-Kind Support to:
 - a. medical societies and patient advocate groups, who are principally involved in issues relating to (i) the treatment of OUD; (ii) the prevention, education, and treatment of opioid abuse, addiction, or overdose, including medication-assisted treatment for opioid addiction; and/or (iii) rescue medications for opioid overdose.

- b. universities, medical institutions, or hospitals, for the purpose of addressing, or providing education on, issues relating to (i) the treatment of OUD; (ii) the prevention, education, and treatment of opioid abuse, addiction, or overdose, including medication-assisted treatment for opioid addiction; and/or (iii) rescue medications for opioid overdose.

D. Lobbying Restrictions⁺

- 1. The Company shall not ~~directly or indirectly~~ Lobby for or against the enactment of any federal, state, or local legislation or promulgation of any rule or regulation that:
 - a. Encourages or requires Health Care Providers to prescribe Opioids or sanctions Health Care Providers for failing to prescribe Opioids or failing to treat pain with Opioids;
 - b. Would have the effect of limiting access to any non-Opioid alternative pain treatments;
 - c. Pertains to the prohibitions against misbranding or adulteration in the Federal Food, Drug, and Cosmetic Act; or
 - d. Pertains to the classification of any Opioid or Opioid Product as a scheduled drug under the Controlled Substances Act.
- 2. The Company shall not directly, or by employing or controlling a Third Party, Lobby against the enactment of any federal, state or local legislation or promulgation of any rule or regulation that supports:
 - a. The use of non-pharmacologic therapy and/or non-Opioid pharmacologic therapy to treat chronic pain over or instead of Opioid therapy, including but not limited to Third Party payment or reimbursement for such therapies~~;~~;
 - b. The use and/or prescription of immediate release Opioids instead of extended release Opioids when Opioid therapy is initiated, including but not limited to Third Party reimbursement or payment for such prescriptions~~;~~;
 - c. The prescribing of the lowest effective dose of an Opioid, including but not limited to Third Party reimbursement or payment for such prescription;

⁺~~[The NCSG believes that Section D should be modified to provide, as it relates to lobbying activities, that the Company shall not directly or indirectly Lobby before the Disposition Event. Parties including the NCSG are in discussions to see if this issue can be resolved.]~~

- d. The limitation of initial prescriptions of Opioids to treat acute pain;
- e. The prescribing and other means of distribution of naloxone to minimize the risk of overdose, including but not limited to Third Party reimbursement or payment for naloxone~~;~~;
- f. The use of urine testing before starting Opioid therapy and annual urine testing when Opioids are prescribed, including but not limited to Third Party reimbursement or payment for such testing~~;~~;
- g. Evidence-based treatment (such as using medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for Opioid Use Disorder, including but not limited to third party reimbursement or payment for such treatment~~;~~; or
- h. The implementation or use of Opioid drug disposal systems that have proven efficacy for the Company's Opioid Products.
- i. ~~3.~~ The Company shall not directly~~,~~, or indirectly by employing or controlling a Third Party, Lobby against the enactment of any federal, state or local legislation or promulgation of any rule or regulation limiting the operation or use of prescription drug monitoring programs ("PDMPs"), including, but not limited to, provisions requiring Health Care Providers to review PDMPs when Opioid therapy is initiated and with every prescription thereafter.
- j. ~~4.~~ The Company shall not establish any Political Action Committees or make campaign contributions to candidates for political office at any time prior to the NewCo Disposition Event.

3. ~~5.~~ Provided, however, that nothing in Section III.D of this injunction limits the Company from:

- a. Challenging the enforcement of, or suing to stop the enactment of, or for declaratory or injunctive relief with respect to any legislation, rules or regulations~~, including legislation, rules or regulations relating to any issues referred to in Section III.D.1.~~;
- b. Responding to a statute, rule, regulation, or order requiring such communication~~;~~;
- c. Appearing before a federal or state legislative or administrative body, committee, or subcommittee as a result of a mandatory order, or subpoena commanding that person to testify~~;~~;
- d. Responding, in a manner consistent with this injunction, to an unsolicited request for the input on the passage of legislation or the promulgation of any rule or regulation when such request is submitted in writing

specifically to the Company from a government entity directly involved in the passage of that legislation or promulgation of that rule or regulation;²

e. Responding to unsolicited requests from the DEA, the FDA, or any other Federal or state agency and/or participating in FDA or other agency panels at the request of the agency;²

~~f. Communications by the Company, including to elected or appointed officials, federal or state legislative or administrative bodies, committees, or subcommittees regarding (i) mechanisms for preventing opioid abuse and misuse, including abuse deterrent formulations and the use of blister packaging for opioid medications, (ii) the prevention, education, and treatment of opioid use disorders or opioid abuse, addiction, or overdose, including medication-assisted treatment for opioid addiction; and/or (iii) rescue medications for opioid overdose; and/or (iv) PHI Products.~~

f. Communicating with governmental officials regarding access to, availability of, procurement of, or use of PHI Products.

g. Monitoring any pending or proposed legislation, rule or regulation relating to its business, including directly or indirectly through grantees or Third Parties.

4. The Company shall not Lobby by affirmatively advocating either for or against the enactment of any federal, state, or local legislation or promulgation of any rule or regulation or the appointment of any individual to public office, unless NewCo's Board shall have determined that the request comports with the Company's Purpose (as defined in the NewCo Operating Agreement). If NewCo's Board so determines, then the Company shall provide advance notice to the Monitor of its intention to Lobby on the issue. The Monitor shall then have the sole and absolute discretion to direct that the activity not take place if the Monitor exercises such discretion and determines that the request approved by the NewCo Board (a) is expressly prohibited by the terms of this injunction, or (b) does not reasonably comport with the Company's Purpose (as defined in the NewCo Operating Agreement). Nothing in Section III.D.4 shall permit advocacy that is otherwise prohibited under Section III.D.

5. ~~6.~~ The Company shall require all of its officers, employees, and agents engaged in conduct described in Section III.D to certify annually in writing or by appropriate electronic means to the Company that they are aware of and will fully comply with the provisions of this injunction with respect to Lobbying on behalf of the Company.

6. On a quarterly basis, NewCo will report its Lobbying activities to the Monitor and the Board. The requirements of Section III.~~2~~.D shall remain in effect until the NewCo Disposition Event.

E. Ban on Prescription Savings Cards

1. The Company shall not directly or through a Third Party offer prescription savings cards or coupons for its Opioid Products (other than PHI Products) except to existing, commercially insured, non-cash paying patients. Nothing in this paragraph shall prohibit the Company from utilizing unsolicited electronic point-of-dispense programs for the benefit of commercially-insured, non-cash paying patients.
2. The Company shall not directly or indirectly assist patients, Health Care Providers, or pharmacies regarding the claims and/or prior authorization process required for third-party payors to approve claims involving any Opioid Product.

F. Monitoring and Reporting of Direct and Downstream Customers

1. The Company shall operate an effective monitoring and reporting system in compliance with 21 C.F.R. § 1301.71(a), 21 C.F.R. §1301.74(b), 21 U.S.C. § 823(d) and Section 3292 of the SUPPORT for Patients and Communities Act and final DEA administrative decisions that are published in the Federal Register.
2. The monitoring and reporting system shall include processes and procedures pertaining to Opioid Products that:
 - a. Utilize all reasonably available information and conduct appropriate due diligence to identify a Suspicious Order of an Opioid Product by a direct customer, including, but not limited to, utilizing appropriate algorithms to identify orders of unusual size, unusual frequency and/or that deviate from a normal pattern.
 - b. Review all Suspicious Orders to determine whether circumstances warrant permitting a Suspicious Order to be cleared for shipment. As part of this review, the Company shall conduct appropriate due diligence including, but not limited to, collecting additional information and documentation from direct customers that explain whether the order is legitimate, and conducting a site visit if warranted. No Suspicious Order may be cleared absent adequate, documented justification.
 - c. In addition to the review above, each month the Company shall make a selection of previously cleared orders for further review. Such additional review will include, but not be limited to gathering information pertaining to the legitimacy of the customer's orders and investigating whether there are indicators that a direct or downstream customer poses a risk of diversion. The Company shall document its review and findings.
 - d. Require all direct customers to annually complete a Wholesaler Due Diligence Questionnaire ("Questionnaire"), utilize all information that the Company receives through such Questionnaire, and require any direct customer that provides incomplete, unsigned, or unresponsive responses,

or fails to provide referenced accompanying information to correct the deficiency. The Company will conduct site visits to corroborate the information obtained from its customers. Once the Questionnaire review process is complete, any Questionnaire that is incomplete, unsigned or unresolved shall result in denial of clearance for shipment.

- e. Utilize all reasonably available Downstream Customer Data to identify whether a downstream customer poses a material risk of diversion of an Opioid Product, including, but not limited to: a monthly review of Downstream Customer Data; review of Downstream Customer Data to identify downstream customers that consistently have a large volume of chargebacks meriting further investigation; the establishment of objective methods for identifying chargeback units that merit further review; and the review of chargeback reports to identify downstream customers that have higher chargebacks on a repeat basis. If chargeback data reveals suspicious indicia (e.g. the number or frequency of chargebacks), the Company shall investigate further. To the extent the inquiry does not resolve the concern, the Company shall report the identity of the downstream customer to DEA and to the relevant direct customers.
- f. Utilize all reasonably available information that the Company receives that indicates an unreasonable risk of a direct customer's or a downstream customer's diversion activity or potential for diversion activity, including reports by the Company's employees, customers, Health Care Providers, law enforcement, state, tribal, or federal agencies, or the media.
- g. Upon request (unless otherwise required by law), report to any requesting State Attorney General or State controlled substances regulatory agency or Department of Justice component any direct customer or downstream customer in such requesting State Attorney General's or agency's State identified as part of the monitoring required by Sections III.F.2(a)-(f), and any customer relationship in such State terminated by the Company relating to diversion or potential for diversion. DEA will be notified of all Suspicious Orders. Additionally, rejected order information will be shared with DEA in compliance with governing statutes and regulations. These reports shall include the following information, to the extent known to the Company:
 - i. The identity of the downstream customer and the direct customer(s) engaged in the controlled substance transaction(s), to include each registrant's name, address, business type, and DEA registration number.
 - ii. The dates of reported distribution of controlled substances by direct customers to the downstream customer during the relevant time period.

- iii. The drug name, drug family or NDC and dosage amounts reportedly distributed.
 - iv. The transaction or order number of the reported distribution.
 - v. A brief narrative providing a description of the circumstances leading to the Company's suspicion that there is a risk of diversion.
 - h. The Company will retain record copies of documentation associated with Sections III.F.2(a)-(g), and make such documentation available to any federal, state, or local law enforcement agency upon request.
- 3. The Company shall not provide to any direct customer an Opioid Product to fill an order identified as a Suspicious Order unless the Company investigates and finds that the identified order is not suspicious. The Company may not find an identified order is not suspicious solely based on a threshold review. Where the Company has reviewed an order identified as a Suspicious Order and determined that the identified order is not suspicious, the Company must document the basis for its determination, and provide such documentation to the Monitor. The Company will retain record copies of documents provided to the Monitor, and make such documentation available to any federal, state, or local law enforcement agency upon request.
 - 4. The Company shall promptly notify the DEA of findings by the Monitor related to the Company's suspicious order monitoring program.
 - 5. The Company shall employ sufficient staff so that the suspicious order monitoring can be robust, the review of customer provided Questionnaires can be thorough, and the documentation of all decisions related to Suspicious Orders can be thorough and complete.
 - 6. Upon request, the Company shall provide full cooperation and assistance to any federal, state or local law enforcement investigations of potential diversion or suspicious circumstances involving Opioid Products, including criminal law enforcement agencies, drug control agencies, professional licensing boards, and Attorney General's offices. For the avoidance of doubt, the Company must provide full cooperation to DEA and any component of the Department of Justice.
 - 7. The Company will refrain from providing an Opioid Product (other than a PHI Product) directly to a retail pharmacy location or Health Care Provider or otherwise engaging in activity that requires it to be registered as a distributor under the Controlled Substances Act. Nothing in this provision, however, prevents the Company from acting as a distributor of PHI Products consistent with applicable law.

G. General Terms

1. To the extent that a provision in this injunction conflicts with federal or relevant state law or regulation, the requirements of the law or regulation will prevail. To the extent that any provision in the injunction is in conflict with federal or relevant state law such that the Company cannot comply with both the statute or regulation and a provision of this injunction, the Company may comply with such statute or regulation. To the extent that the Company makes any such determination, it will disclose the conflict and its determination to the affected State Attorney(s) General, the Director, Consumer Protection Branch, Department of Justice, and the Monitor as soon as reasonably practicable and in advance of any change to the Company's policies or practices.
2. The Company shall not make any written or oral statement about Opioids, Opioid Products or PHI Products that is unfair, false, misleading or deceptive, or unconscionable.
3. The Company shall not represent that Opioids, Opioid Products or PHI Products have approvals, characteristics, uses, benefits, or qualities that they do not have or are inconsistent with the products' FDA-approved labeling.
4. For the avoidance of doubt, nothing in this injunction is intended to or shall be construed to prohibit the Company in any way whatsoever from taking legal or factual positions with regard to its Opioid Product(s) in defense of litigation or other legal proceedings or investigations.
5. Upon the request of any State Attorney General or federal component, the Company shall provide the requesting State Attorney General or federal component with the following, within 30 days of the request:
 - a. Notification as to whether the Company has received any litigation or civil or criminal law enforcement subpoenas or Civil Investigative Demands relating to the Company's Opioid Product(s), as well as the identity of the state~~(s)~~ or federal component(s) that issued any such subpoenas or Civil Investigative Demands.
 - b. Copies of warning or untitled letters issued by the FDA regarding the Company's Opioid Product(s) and all non-confidential correspondence between the Company and the FDA related to such letters.
6. Whenever possible, each provision of this injunction shall be interpreted in such manner as to be effective and valid under applicable law and regulation, but if any provision of this injunction is held to be prohibited by or invalid under applicable law, such provision shall be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of this injunction.

H. Compliance with All Laws and Regulations Relating to the Sale, Promotion, and Distribution of Any Opioid Product

1. The Company shall comply with all laws and regulations that relate to the sale, Promotion, distribution, and disposal of any Opioid Product or PHI Product including but not limited to:
 - a. State controlled substances acts.
 - b. The Federal Controlled Substance Act and any regulation promulgated thereunder.
 - c. The Federal Food, Drug and Cosmetic Act, or any regulation promulgated thereunder.
 - d. Federal health care offenses, as defined in 18 U.S.C. § 24.
 - e. State consumer protection and unfair trade practices acts.
 - f. State laws and regulations related to prescribing, distribution and disposal of Opioid Products.
 - g. Bribery, Foreign Corrupt Practices Act, Anti-Kickback, and Stark laws and regulations.

I. Compliance Deadlines

1. As of 90 days after the Effective Date, the Company must be in full compliance with the provisions included in this injunction.

J. Training

1. The Company shall provide regular training, at least once per year, to relevant employees on their obligations imposed by this injunction. The Company shall provide training to any new employees at the time of their onboarding.

IV. CLINICAL DATA TRANSPARENCY

A. Data to Be Shared

1. The Company shall share the following clinical data to the extent and in a manner permitted by applicable law and contracts, including data privacy laws, informed consent forms and clinical trial protocols through a third-party data archive that conforms to the requirements defined below to increase the transparency of its clinical research.
 - a. The Company shall make available all clinical data and/or information it possesses in electronic form that can be located following a reasonably diligent search, regarding OxyContin® Tablets, Butrans® Transdermal System and Hysingla® Tablets previously disclosed to the FDA².

- b. The Company shall make available all previously unreleased, clinical data it possesses in electronic form that can be located following a reasonably diligent search, regarding OxyContin® Tablets, Butrans® Transdermal System and Hysingla® Tablets, for both approved and unapproved indications, including:
 - i. Full analyzable data set(s) (including individual participant-level data de-identified by an independent biostatistician);
 - ii. The clinical study report(s) redacted for commercial or personal identifying information;
 - iii. The full protocol(s) (including the initial version, final version, and all amendments); and
 - iv. Full statistical analysis plan(s) (including all amendments and documentation for additional work processes) and analytic code.

B. Third-Party Data Archive

1. The Company shall share the ~~above~~-clinical data and information described in Section IV.A.1 via a third-party data archive that makes clinical data available to Qualified Researchers with a bona fide scientific research proposal.
2. The Company shall begin sharing information identifying the clinical data and information described in Section IV.A.1.a and b with the vendor no later than 30 days following entry of the Confirmation Order and shall complete that process of identifying the clinical data and information described in Section IV.A.1.a and b no later than 90 days following entry of the Confirmation Order.
3. The data archive shall have a panel of reviewers with independent review authority to determine whether the researchers are qualified, whether a research application seeks data for bona fide scientific research, and whether a research proposal is complete.
4. The panel may exclude research proposals with a commercial interest.

C. Non-Interference

1. The Company shall not interfere with decisions made by the staff or reviewers associated with the third-party data archive.
2. Unless expressly stated herein, the Company shall have no communications directly or indirectly with a Qualified Researcher, including with regard to the data added to the third party archive.

D. Data Use Agreement

1. Any data sharing agreement with a Qualified Researcher who receives shared data via the third-party data archive shall contain contact information for the Company's pharmacovigilance staff. Every agreement shall require the lead qualified researcher to inform the Company's pharmacovigilance staff within 24 hours of any determination that research findings could detrimentally impact the risk-benefit assessment regarding the product. The ~~lead Qualified Researcher may also inform regulatory authorities of the safety signal impacting the risk-benefit assessment after reasonable notice to the Company.~~ ~~The~~ Company's pharmacovigilance staff shall take all necessary and appropriate steps upon receipt of such safety information, including but not limited to notifying regulatory authorities or the public. The lead Qualified Researcher may also inform regulatory authorities of the safety signal impacting the risk-benefit assessment as well as provide reasonable notice to the Company.

E. Cost

1. The Company shall bear all costs for making data and/or information until the NewCo Disposition Event.

V. DISPUTE RESOLUTION

- A. For the purposes of resolving disputes with respect to compliance with this injunction, should any State Attorney General or federal agency have reason to believe that the Company has violated a provision of this injunction subsequent to the Effective Date, then such Attorney General or federal agency shall notify the Company in writing of the specific objection, identify with particularity the provisions of this injunction that the practice appears to violate, and give the Company 30 days to respond to the notification.
- B. Upon 30 days of receipt of written notice from such State Attorney General or federal agency, the Company shall provide a written response, containing either a statement explaining why the Company believes it is in compliance with this injunction or a detailed explanation of how the alleged violation occurred and a statement explaining how and when the Company intends to remedy or has remedied the alleged violation.
- C. Such State Attorney General may not take any action concerning the alleged violation of this injunction during the 30-day response period. Nothing shall prevent such State Attorney General from agreeing in writing to provide the Company with additional time beyond the 30 days to respond to the notice. However, such State Attorney General may take any action, including, but not limited to legal action to enforce compliance with the [Confirmation Order/consent judgment specified by Section II.B], without delay if such State Attorney General believes that, because of the specific practice, a threat to the health or safety of the public requires immediate action.
- D. Such State Attorney General may bring an action against the Company to enforce the terms of the [Confirmation Order/consent judgment specified by Section II.B], but only after providing the Company an opportunity to respond to the notification as described

above or within any other period as agreed to by the Company and such State Attorney General.

- E. Nothing in this injunction shall be interpreted to limit any State Attorney General's Civil Investigative Demand ("CID") or investigative subpoena authority and any federal agency's subpoena or investigative authority, to the extent such authority exists under applicable state or federal law. The Company agrees to comply with such CID, subpoenas, or other demands or requests issued pursuant to such authority.
- F. Nothing herein shall be construed to exonerate any failure to comply with any provision of this injunction after the Effective Date, or to compromise the authority of any State Attorney General to take action for any failure to comply with this injunction.

VI. INDEPENDENT MONITOR

A. Monitor Selection and Engagement

- 1. The Company shall engage a Monitor to review its compliance with this injunction.
- 2. Steven Bullock, the Monitor approved by the Bankruptcy Court on March 1, 2021 to oversee compliance with the Voluntary Injunction, shall continue to serve as Monitor with respect to this injunction after the Effective Date.
- 3. If a new Monitor must be appointed due to the Monitor resigning or otherwise becoming unable to perform the specified tasks, the TopCo Managers shall select a new Monitor, who must be approved by the State Monitor Committee which approval shall not be unreasonably withheld and approved by the Court. The selected Monitor approved by the State Monitoring Committee may serve while Court approval is pending.
- 4. The Monitor may employ or retain personnel who have appropriate qualifications related to the pharmaceutical industry and the laws governing the manufacture, marketing and sale of pharmaceuticals and controlled substances and the applicable requirements of federal and state law. The Monitor may also retain the services of additional third-parties to the extent that additional expertise is required for the engagement. The Monitor may consult with and seek input from the Company and the State Monitor Committee prior to finalizing the retentions described in this paragraph.

B. Term

- 1. The Company shall retain a Monitor until the NewCo Disposition Event(s).
- 2. As required under Section II.A, any person or entity that acquires some or all of the Company's Opioid Products, including through the NewCo Disposition Event,

shall retain the Monitor for at least one (1) year after the effective date of the transaction.

C. Monitor's Scope of Work

1. The Monitor shall review the Company's ongoing compliance with the requirements of this injunction.
2. The Monitor will report his or her findings as provided in Section VI.F.
3. In the event that in the course of reviewing the Company's compliance with the requirements of this injunction the Monitor becomes aware of action or conduct by the Company that the Monitor believes may pose a threat to the health or safety of the public or otherwise requires prompt action, the Monitor may in his or her sole discretion, notify the Company and the States of such action or conduct without following the procedures provided in Section VI.F below.
4. Within thirty (30) calendar days after the Effective Date, the State Monitor Committee and the Company shall confer with the Monitor on a work plan and contract. In the event a new Monitor is appointed within thirty (30) days prior to the Effective Date, the State Monitor Committee and the Company shall have sixty (60) days from the Effective Date to confer with the Monitor on a work plan and contract. The work plan shall set forth the substance of the Monitor's review and the manner in which the Monitor will carry out his or her review of the Company's compliance with this injunction, including the general scope of information that the Monitor will seek to review. The Monitor shall have final authority to determine the content and substance of the work plan. The Monitor may select the period of time covered by the work plan, not to exceed one year. Any work plan and contract in place before the Effective Date may continue to be used upon agreement of the State Monitor Committee, the Company, and the Monitor.
5. At least annually, and more frequently if appropriate, the Company and the State Monitor Committee will meet in person or virtually to discuss the monitorship and any suggestions, comments, or improvements the Company may wish to discuss with or propose to the State Monitor Committee, unless the Company and the State Monitor Committee believe such a meeting is unnecessary.

D. Monitor Access to Information

1. In connection with its review of the Company's compliance with this injunction, the Monitor shall be vested with broad discretion to review the Company's operations, including access to documents and the right to interview employees, as the Monitor determines is reasonably necessary to fulfill its duties under this injunction, with reasonable notice to the Company and without unreasonable interference in the Company's or its employees' ability to perform day-to-day operations. The Monitor shall have all powers reasonable and necessary to

efficiently and effectively discharge its responsibilities subject to appropriate confidentiality.

2. The Company's General Counsel or his designee shall serve as the primary point of contact for the Monitor to facilitate the Monitor's reasonable access to documents, materials, or employees necessary to review for compliance with this injunction. The Monitor shall have unfettered access to the Chief Compliance Officer. The Monitor shall make a good faith effort to leverage the Company's existing compliance mechanisms when reviewing the Company's compliance with this injunction. The Monitor shall communicate any request for documents, materials, or access to employees to the [General Counsel or his designee], but, subject to the terms hereof, is not prohibited from speaking with any other current or former employees of the Company.
3. The Company shall not intimidate, harass, threaten, or penalize any employee or former employee for his or her cooperation with or assistance to the Monitor.
4. If at any time the Monitor reasonably believes that there is undue delay, resistance, interference, limitation, or denial of access to any records or to any employee deemed necessary by the Monitor to implement or review compliance by the Company with this injunction, the Monitor may meet and confer with the Company's [General Counsel or his designee]. If the Monitor cannot resolve such limitation or denial, it shall be immediately reported to the Board of NewCo. If the issue remains unresolved after consultation with the Board of NewCo, the Monitor shall report the issue to the State Monitor Committee.

E. Access to Monitor

1. There shall be no limitation on the ability of the Monitor to communicate at any time with States and the United States, including any agency or component of the United States, regarding the Company's conduct.

F. Monitor Reports

1. Observations and Recommendations
 - a. If the Monitor notes any areas for potential improvement regarding the Company's compliance with this injunction during the course of his or her reviews, the Monitor shall include any such recommendations in the Final Report described below.
 - b. Collectively, any such questions, concerns or recommendations will be referred to as "Observations and Recommendations."
2. Draft and Final Reports

- a. For purposes of the reporting described below, the Monitor's work will be divided into three-month periods ("Reporting Periods").
- b. No later than ten (10) calendar days after the close of a Reporting Period and/or at any other time deemed reasonably necessary by the Monitor, the Monitor shall provide the Company and the State Monitor Committee with a draft report identifying and detailing any Observations and Recommendations and Potential Violations and the bases therefore (the "Draft Report"). Potential Violations shall mean the Company's failure to comply with the provisions of this injunction, as reasonably determined by the Monitor. The Company shall have the right to cure any Potential Violation, in accordance with the below provisions. The Draft Report will also contain detailed descriptions of any Observations and Recommendations for Improvement.
- c. Within seven (7) calendar days of its receipt of the Draft Report, the Company will provide comments to the Draft Report. The Company may also:
 - i. Respond to each Potential Violation, including, where appropriate, explaining why no violation occurred, or describing any corrective action taken (or to be taken) as a result of the findings made by the Monitor, including, where appropriate, providing documentation supporting a relevant decision or additional context explaining the Potential Violation and why it occurred.
 - ii. Respond to each Observation and Recommendation for Improvement.
- d. After receipt of the Company's comments and responses and the State Monitor Committee's comments, if any, the Monitor will provide a final report (the "Final Report") simultaneously to the State Monitor Committee and the Company.
- e. The Final Report shall set forth:
 - i. The Monitor's evaluation of the Company's compliance with this injunction and the factual basis for the Monitor's conclusions, including whether a Potential Violation has occurred and an explanation of the nature of the Potential Violation.
 - ii. The Monitor's conclusion as to whether the Company has cured any Potential Violations.
 - iii. The Final Report shall include a listing of the Observations and Recommendations for Improvement made by the Monitor and

responses of the Company. Recommendations shall not be deemed to be incorporated into the terms of this injunction.

- iv. The Monitor shall create a public version of each Final Report. The public version of each Final Report shall exclude all information that the Monitor determines, in consultation with the Company, to be trade secret or otherwise commercially sensitive and shall be posted on the Company's website.

VII. SHAREHOLDER RELEASED PARTIES

- A. The Shareholder Released Parties shall not take any action that would interfere with the Company's compliance with its obligations under this injunction.

Summary report: Litera® Change-Pro for Word 10.14.0.46 Document comparison done on 8/31/2021 10:12:41 PM	
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Intelligent Table Comparison: Active	
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Delete	37
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Move To	3
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Table Delete	0
Table moves to	0
Table moves from	0
Embedded Graphics (Visio, ChemDraw, Images etc.)	0
Embedded Excel	0
Format changes	0
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